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PATENT

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Attorney Reference Number 7228-70063-01
Application Number 10/616,122Remarks

After entry of this amendment, claims 1-13, 15-29, 33-36, and 40-54 are pending. Claims 3-6, 11, 17-24, 28-29, 34-36, 41 and 44 have been amended. Claims 3-6, 11, 17-21, and 23-24 have been amended to use the standard transitional word "comprising," and not for the statutory requirements for patentability. Claims 34 and 41-42 have been amended to correct their dependency while claim 44 has been amended to correct a minor typographical error. Applicant intends for amended claims 3-6, 11, 17-21, 23-24, 34, 41-42, and 44 to be interpreted at least as broadly as the originally filed claims. Claims 14, 30-32, and 37-39 are cancelled. Claims 49-54 have been added. Support for added claims 49-54 can be found in the originally filed specification at page 15, paragraph 46. No new matter is added by this Amendment A.

Rejection Under §103(a) Over Salansky and Schmeller

Claims 1-24 and 35-42 stand rejected under 35 U.S.C. §103(a). The Office Action states that these claims are obvious over Schmeller et. al, "Tissue oxygenation and microcirculation in lipodermatosclerosis with different extent of erythema around venous ulcers," *VASA*, 26, 18-24 (1997) ("Schmeller") and U.S. Patent No. 6,494,900 to Salansky ("Salansky"). The Office states that Salansky teaches that edema and inflammation can be treated by exposure to laser radiation having a wavelength in the range of 400 to 2000 nm and that it would be obvious to use this teaching to treat lipodermatosclerosis, in light of the Office's statement that Schmeller teaches that lipodermatosclerosis involves erythema.

According to MPEP § 706.02(j), for a claim to be obvious, there must be a) a suggestion or motivation in the references to combine reference teachings, b) a reasonable expectation of success, and c) the references must teach all of the claim limitations, *In re Vaeck*, 947 F.2d 488,

20 U.S.P.Q.2d 1438 (Fed. Cir. 1991). While the Office focuses on Salansky's use of laser radiation having a wavelength of 400 to 2000 nm, this wavelength range is not recited in the rejected claims. Rather, independent claims 1 and 11 contain limitations related to the depth to which the laser radiation penetrates the skin. Independent claims 22 and 35, as amended, specify that the applied laser radiation includes a first wavelength absorbed by oxygenated hemoglobin and a second wavelength absorbed by deoxygenated hemoglobin. As discussed in Applicant's disclosure at page 3, paragraphs 8-9, de-oxygenated hemoglobin may be treated at comparatively deep skin depths, such as depths to about 6-7 millimeters, while oxygenated hemoglobin may be treated at relatively shallow depths, such as depths to about 3-4 millimeters. Applicant teaches that the disclosed methods can be used to treat various skin conditions, including induration, hyperhidrosis and weeping, brawny or leathery skin, hyperpigmentation, and pain and discomfort. Page 11, paragraph 32.

Salansky discusses depth of radiation penetration at column 10, line 7 through column 11, line 30. However, the only penetration depths suggested by Salansky are relatively shallow. For example, Table 4 lists examples of penetration depths. The deepest penetration listed in Table 4 is only 1.7 millimeters. Similarly, Figure 2, a graph of incident radiation penetration by skin depth, does not display values for skin depths greater than 2 millimeters. Figure 3, a graph of fluence versus skin depth, shows peak fluence at less than 2.5 millimeters, very little fluence at 5 millimeters, and almost no fluence at a depth of 7.5 millimeters. Moreover, even though Figure 3 extends to depths of 4.950 centimeters, Salansky appears to contain no statements that would suggest that the data in Figure 3 indicates that laser radiation can be used to treat skin conditions at comparatively deep depths. In fact, the peak fluence at less than 2.5 millimeters is consistent with the other statements and disclosure of Salansky, all of which appear to be limited

to skin depths of less than 2 millimeters. Accordingly, rather than teaching or suggesting the use of radiation that penetrates to relatively deep depths, including in conjunction with treatment with radiation that penetrates to relatively shallow depths, Salansky teaches away from the use of such radiation by focusing solely on radiation penetrating to relatively shallow depths.

Because Salansky does not teach or suggest applying laser radiation to the skin to a depth of more than 2 millimeters, at most, it does not meet the limitation of claim 1 requiring laser radiation penetrating to a depth exceeding 4.5 millimeters. Similarly, Salansky does not teach or suggest treating skin using one laser having a laser wavelength penetrating to a relatively shallow depth and another laser having a wavelength penetrating to a relatively deeper depth than the wavelength of the one laser, as required by claim 11. Salansky does not teach or suggest using a first laser having a first wavelength absorbed by hemoglobin and melatonin and a second laser having a second laser wavelength absorbed by de-oxygenated hemoglobin, as required by amended claims 22 and 35. Moreover, Salansky, nor its combination with Schmeller, teaches the advantages which can be realized from using the presently claimed methods.

Another reason that the present claims are patentable over Salansky and Schmeller is that neither of these references, nor their combination, provides any specific guidance on treating lipodermatosclerosis and the other conditions recited in Applicant's claims. Although the Office suggested that it would be obvious to use the methods of Salansky to treat such conditions based on Schmeller's statement that lipodermatosclerosis involves erythema, Salansky discusses numerous configurations that can supposedly be used to treat inflammation. Neither Salansky, Schmeller, nor their combination teaches or suggests which of the numerous inflammation treatments discussed in Salansky would be suitable for treating lipodermatosclerosis and the other conditions recited in the pending claims.

Accordingly the combination of Salansky and Schmeller does not teach or suggest all limitations of claims 1, 11, 22, and 35. Claims 2-10, 12, 13, 15-21, 23-24, 36, 40-42, and 49-51 are allowable by virtue of their dependency from allowable independent claims. The Applicant respectfully requests reconsideration and withdrawal of the §103 rejection of claims 1-13, 15-24, 35-36, and 40-42.

Rejection Under §103(a) Over Salansky, Schmeller, and Baranov

Claims 25-34 stand rejected under 35 U.S.C. §103(a). Claims 30-32 have been cancelled.

The Office stated that claims 25-34 were obvious over Schmeller and Salansky, in further view of U.S. Patent No. 6,632,219 to Baranov et. al. (Baranov). The Office stated that Baranov teaches the use of 532 nm radiation to treat skin disorders. Applicant notes that the use of lasers having a wavelength of 532 nm is specifically recited only in claims 25-27; and is not recited in claims 28-34. Claim 22, from which claims 25-34 depend, is allowable over the Schmeller and Salansky. Accordingly, claims 25-29, 33-34, and 52-54 are also allowable. Additionally, although the Office asserts that Baranov teaches the use of 532 nm radiation, none of the cited references, or their combination, suggest the specific benefits that flow from using 532 nm radiation in conjunction with radiation having a wavelength of 1064 nm, as specified in claims 25-27. Applicant respectfully requests reconsideration and withdrawal of the §103(a) rejection of claims 25-29 and 33-34.

Further Arguments for the Patentability of Dependent Claims

Although dependent claims 2-10, 12, 13, 15-21, 23-27, 29, 33-34, 36, 40-42, and 44-54 are allowable by virtue of their dependence from an allowable independent claim, as discussed above, there are additional reasons why the pending dependent claims are allowable.

For example, the cited combinations of references do not teach the use of laser radiation that penetrates to a depth exceeding 5.5 millimeters below the skin surface or where the laser radiation is applied for a period of time sufficient to damage hemoglobin through the depth exceeding 5.5 millimeters below the skin surface, as specified in claims 2 and 44. Similarly, the cited combinations of references do not teach or suggest methods of skin treatment involving damaging hemoglobin using radiation penetrating to a depth exceeding 4.5 millimeters, as recited in claims 45 and 46. The cited combinations of references do not teach repeated treatments with laser radiation penetrating to the claimed depths, or using radiation that damages, or is absorbed by, specific skin components, as specified in claims 3-6, 17-21, 23-24, 29, 36, 51 and 54. Unlike claims 12 and 13, the cited combination of references do not teach or suggest using a laser that penetrates to a relatively shallow depth using a wavelength absorbed by oxygenated hemoglobin or using a laser that penetrates to a relatively deeper depth than the relatively shallow depth using a wavelength absorbed by de-oxygenated hemoglobin. Similarly, the cited combinations of references do not teach using a laser having a wavelength absorbed by melanin, as discussed in claims 15 and 16, or that the radiation damages melanin, as specified in claim 47. In addition, the cited combinations of references do not teach or suggest simultaneous treatment with multiple wavelengths, as specified in claims 49 and 52.

Conclusion

For all of the above reasons, Applicant submits that the present application is in condition for allowance. If the Examiner has any questions regarding the application or this response, the Examiner is encouraged to call Applicant's attorney, Ryan A. Heck, at (775) 824-0104.

Respectfully submitted,

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